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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,845	02/09/2006	Rudolf-Giesbert Alken	82445	5014

23685 7590 02/16/2007
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EXAMINER

NAGUBANDI, LALITHA

ART UNIT	PAPER NUMBER
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1621

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/539,845

Applicant(s)

ALKEN, RUDOLF-GIESBERT

Examiner

Lalitha Nagubandi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 34-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 34-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

Status of the Claims

Claims 1-11 and 34-63 are pending. Claims 12-33 have been canceled. Claims 1-11 and 34-63, are considered in this office action.

Priority

This application is a 371 of PCT/GB03/04203 dated December 18th, 2003, which claims priority to German application no. 10261807.0 dated December 18th, 2002.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

Claim Rejections - 35 USC § 112

Claims 34-41 and 49-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 34-41 and 49-56 provides for the use of deuterated catecholamine derivatives, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 34-41 and 49 – 56 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

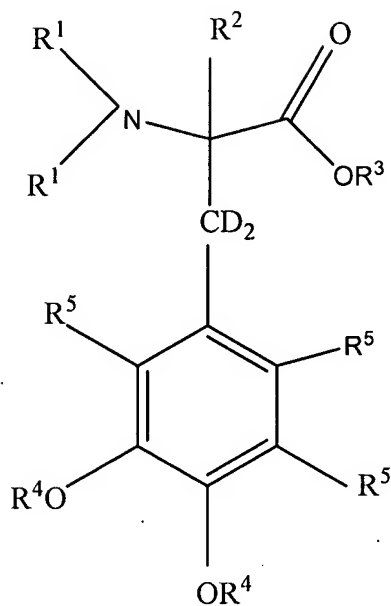
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al (J. Chem. Soc. (C), 1970, page 2049-2051)

The instant claims are directed to deuterated catecholamine derivatives of the general **formula I** as embodied in claim 1,2,9 and 10 where the β -carbon is dideuterated as shown.

**Formula I**

Bennett et al disclose (see column 1, 2nd para, page 2050, J. Chem. Soc. (C), 1970, page 2049-2051) 3,4-dihydroxy [β - $^2\text{H}_2$] phenylalanine, thus anticipating the instant claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

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patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1- 11, 42- 48 and 57-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett et al ((J. Chem. Soc. (C), 1970, page 2049-2051), and Chen et al (Biotechnology Letters, volume 14 No. 4 (April 1992) pp. 269-274) in view of Milstien et al (The Journal of Biological Chemistry, Vol. 250, No. 12, Issue of June 25, pp. 4782-4785, 1975).

The instant claims are directed to various deuterated catecholamine derivatives of the general **formula I**. Further, pharmaceutical compositions containing deuterated catecholamine derivatives are embodied in the instant application.

Determination of Scope and content of the Prior Art (MPEP § 2141.01)

Bennett et al teach deuterated 3,4 dihydroxy phenylalanine (β -deuterated amino acid) (see column 1, 2nd para, page 2050, J. Chem. Soc. (C), 1970, page 2049-2051) and

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Chen et al teach preparation of optically pure [α - ^2H]- α -amino acids (α -deuterated amino acids) (see page Scheme I, page 270, Biotechnology Letters, volume 14 No. 4 (April 1992) pp. 269-274) and further Milstien et al teach 2,3,4,5,6-pentadeutero-L-phenylalanine (see column 1 page 4783, para.3, The Journal of Biological Chemistry, Vol. 250, No. 12, Issue of June 25, pp. 4782-4785, 1975 and see the whole document).

Ascertainment of the difference between the Prior Art and Claims (MPEP §2141.02)

The difference between the instant compounds and Bennett et al is that some of the instant compounds require deuteration at the ring, and at α carbon. Bennett et al teaches the deuteration of only at the β -carbon of the amino acid. Chen teaches the deuteration at the α carbon and also at the ring but the reference is silent about the 3,4 dihydroxy groups. Milstien teaches studies on the phenylalanine hydroxylase system in vivo. Milstein is silent about the deuterated catecholamine derivatives.

Finding of prima facie obviousness – rational and motivation (MPEP § 142-2143)

Accordingly, one of ordinary skill in the art would be motivated to prepare the instant compounds by modifying the substitutions around the core structure, since the dideuterated catecholamine derivative is anticipated. Substitution of the N-H or O-H or the carboxylic H with deuterium would have been obvious to one skilled in the art. The examiner contends that the combination of references is proper and an ordinary artisan would have had a reasonable expectation of success at the time of the instant invention to arrive at the instant compounds/compositions and hence it is prima facie

Conclusion

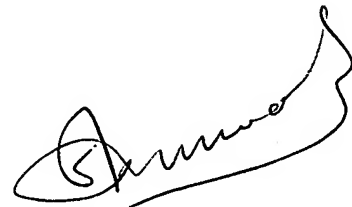
No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalitha Nagubandi whose telephone number is 571 272 7996. The examiner can normally be reached on 6.30am to 3.30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lalitha Nagubandi
Patent Examiner
Technology Center 1600

February 15th, 2007.



Shailendra Kumar
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